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A prospective, randomised, controlled study examining binaural beat audio and pre-operative anxiety in patients undergoing general anaesthesia for day case surgery*

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Summary

Pre-operative anxiety is common and often significant. Ambulatory surgery challenges our pre-operative goal of an anxiety-free patient by requiring people to be 'street ready' within a brief period of time after surgery. Recently, it has been demonstrated that music can be used successfully to relieve patient anxiety before operations, and that audio embedded with tones that create binaural beats within the brain of the listener decreases subjective levels of anxiety in patients with chronic anxiety states. We measured anxiety with the State-Trait Anxiety Inventory questionnaire and compared binaural beat audio (Binaural Group) with an identical soundtrack but without these added tones (Audio Group) and with a third group who received no specific intervention (No Intervention Group). Mean [95% confidence intervals] decreases in anxiety scores were 26.3% [19–33%] in the Binaural Group ($p = 0.001$ vs. Audio Group, $p < 0.0001$ vs. No Intervention Group), 11.1% [6–16%] in the Audio Group ($p = 0.15$ vs. No Intervention Group) and 3.8% [0–7%] in the No Intervention Group. Binaural beat audio has the potential to decrease acute pre-operative anxiety significantly.

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A high level of pre-operative anxiety is commonplace in adult patients [1–3]. Worries about loss of control, being in an unfamiliar environment and the perceived risk of morbidity and mortality all contribute to this unpleasant phenomenon. Evidence of heightened pre-operative anxiety is not always specifically sought by anaesthetists [1] despite demonstrations that it increases intra-operative anaesthetic requirements [3] and postoperative pain [4, 5]. Patients with a low predisposition to anxiety who become apprehensive whilst awaiting surgery may develop gastric stasis [6].

Day case surgery combines the need for a 'street ready' patient soon after surgery with the goal of low pre-operative anxiety. Traditional pharmacological anxiolysis fails to meet these aims [7] and, as part of a more rational approach, pre-operative psychological preparation has become recognised as a potential route towards achieving these contrasting goals. The value of music in decreasing anxiety before surgery has been demonstrated in a number of recent studies [8–10]. However, music is limited in its ability to produce anxiolysis, being dependent on the nature and rhythm of the music, e.g. the Mozart Effect [11], and the associations generated by the listener.

Binaural beats were first described by Oster [12] over 30 years ago. They are produced within the brain in response to two similar pure tones being presented separately to each ear. The rhythm of the binaural beat equals the difference between the two tones and, if sustained, this rhythm can be entrained throughout the brain. The frequency of the binaural beat can thus be selected to produce particular EEG-associated states.

Inducing brain-wave states with binaural beats has been used to decrease anxiety in patients suffering from chronic anxiety. Binaural beat audio rich in delta brain-wave

entrainment confers the greatest anxiolysis [13]. We chose a commercially available 30-min audio track (Holosync Solution (Awakening Prologue), Centerpointe Research Institute, Beaverton, OR), which generates a progressive slowing of the binaural beat to give a closing 10-min period of delta activity. We examined the effect of binaural beat audio on pre-operative acute anxiety scores as measured by the State-Trait Anxiety Inventory (STAI) self-evaluation questionnaire [9, 14].

Methods

After approval from the Local Research Ethics Committee, the study was conducted over a 6-month period (October 2003 to March 2004). This prospective, randomised, controlled study recruited 108 patients scheduled to undergo general anaesthesia for elective surgery at the Day Surgery Unit at Sunderland Royal Hospital. Individuals with a history of epilepsy, aged < 16 years or with a history of profound deafness were excluded. All participants provided written, informed consent after receipt of written information and having been given the opportunity to ask questions of the investigators.

On the day of surgery, 45–60 min before the operation, the subjects were asked to complete the State-Trait Anxiety Inventory [14] (STAI) questionnaires. The State-Trait Anxiety Inventory is a validated 40-item self-report measure that contains 20 items measuring state anxiety (STAI-S) and 20 items measuring trait anxiety (STAI-T). Scores for state and trait components each range from 20 to 80 with a higher score corresponding to higher anxiety levels. These scores were subsequently converted to a percentage scale.

Subjects were then allocated to one of three groups according to a predetermined computer-generated random sequence. Participants listened for 30 min to binaural beat audio (Binaural Group) or an identical soundtrack without these added tones (Audio Group), or received no specific intervention, representing standard practice (No Intervention Group).

Participants receiving no intervention were allowed to read or watch television, while those listening to audio were taken to a quiet environment and were asked to listen to the music with their eyes closed. An investigator was in attendance throughout this period. Audio was delivered via standard headphones (Philips Electronics HP 140, Eindhoven, the Netherlands) with a frequency range of 15 000–22 000 Hz via six identical compact disc players (Tamashi CD420, China) numbered one to six. Both listener and investigator were blinded as to which three compact discs contained binaural beats and which three compact discs contained audio alone. The allocation of compact discs was determined and stored until the end of the study by the hospital statistician (A.H.), who was blinded to the nature of each disc, having received three compact discs labelled 'A' and three compact discs labelled 'B' from the principal investigator. The study was therefore triple-blinded between the Binaural and Audio Groups, but blinding was not possible for the No Intervention Group.

At the end of the 30-min period, participants completed only the STAI-S portion of the STAI questionnaire for a second time.

Based on the data provided by previous studies [9, 13], a sample size of 34 in each of the three groups was calculated as being necessary to provide 90% power at the 5% two-sided level to detect a difference in means characterised by a variance in means of 13% and a common standard deviation of 10%. Thirty-six patients were recruited to each group. Statistical analysis was performed with SPSS for Windows Version 12.0. Distributions were tested for normality before analysis with the Shapiro–Wilk test. The matched-pairs *t*-test was used to examine within-group differences, and analysis of variance was used to look at between-group differences pre-intervention and postintervention.

Results

Of the 108 subjects who participated in the study, four were excluded as they were unable to complete the process. One participant disliked the music provided (Audio Group) and three subjects (one from each group) did not complete the second STAI-S questionnaire for logistical reasons. No adverse events were noted.

There was no significant difference in STAI-T scores between groups (Table 1), but initial STAI-S scores were higher in the Binaural Group than in the other two groups. The mean [95% CI] decrease in anxiety (STAI-S) scores from initial testing to postintervention testing was 26.3% [19–33%] for the Binaural Group ($p = 0.001$ vs. Audio Group, $p < 0.0001$ vs. No Intervention Group), compared to 11.1% [6–16%] in the Audio Group ($p = 0.15$ vs. No Intervention Group) and 3.8% [0–7%] in the No Intervention Group. As the pre-intervention STAI-S scores differed between groups, the initial STAI-S scores were entered as a covariate into a general linear model (Analysis of Covariance – ANCOVA) in order to adjust for bias and to produce adjusted postintervention STAI-S scores (Table 2).

All three groups contained a minority of participants whose STAI-S scores increased as their procedure became imminent. Significantly fewer participants recorded an increase in STAI-S anxiety in the Binaural Group than in the Audio Group or the No Intervention Group (Table 3).

Table 1 Patient characteristics and baseline anxiety scores. Values are number or mean [95% CI].

	Binaural Group $n = 35$	Audio Group $n = 34$	No Intervention Group $n = 35$
Sex; M : F	12 : 23	12 : 22	15 : 20
Time of operating list; morning: afternoon	12 : 23	15 : 19	23 : 12
Surgical subspecialty; gynaecology : general surgery : urology	19 : 11 : 5	21 : 7 : 6	16 : 14 : 5
Initial STAI-T score; %	38.2 [35–42]	35.4 [33–41]	
Initial STAI-S score; %	51.6 [48–55]*	40.5 [37–44]*	42.8 [39–47]*

*Statistically significant difference between groups (ANOVA): $p < 0.0005$.
STAI-T: State-Trait Anxiety Inventory-Trait. STAI-S: State-Trait Anxiety Inventory-State.

Table 2 Adjusted postintervention STAI-S scores obtained via analysis of covariance, using initial STAI-S scores as a covariate. Values are mean [95% CI].

	Binaural Group $n = 35$	Audio Group $n = 34$	No Intervention Group $n = 35$
Adjusted Post-intervention STAI-S score; %	19.2 [14–24]*	28.0 [23–33]†	36.6 [32–41]

Abbreviations as for Table 1.
*$p < 0.001$ vs. No Intervention Group; $p = 0.053$ vs. Audio Group.
†$p = 0.039$ vs. No Intervention Group.

Table 3 Comparison of initial STAI-S scores with postintervention STAI-S scores.

	Binaural Group $n = 35$	Audio Group $n = 34$	No Intervention Group $n = 35$
Subjects showing an increase in STAI-S score; *n*	2*	8	11
Subjects showing a decrease in STAI-S score; *n*	32	26	20
Subjects showing no change in STAI-S score; *n*	1	0	4

Abbreviations as for Table 1.
*$p = 0.045$ vs. Audio Group; $p = 0.012$ vs. No Intervention Group.

Discussion

Audio embedded with tones that generate binaural beats within the brain of the listener produces a predictable alteration in brain-wave activity. Binaural beats are auditory brainstem responses that are believed to originate in the superior olivary nucleus. This waxing and waning in loudness possesses a frequency equal to the difference between the two pure tones presented, provided the original impulses are < 1000 Hz and the difference between the two tones is between 1 Hz and 30 Hz. For example, if a pure tone of 400 Hz is presented to the right ear and a pure tone of 410 Hz is presented simultaneously to the left ear, an amplitude-modulated standing wave of 10 Hz is experienced as the two sound waves merge in and out of phase. This phase difference normally provides directional information on low frequency sounds [12]. If sustained binaural beat frequencies resonate throughout the brain via the 'frequency following response' (FFR), this can cause alterations in levels of arousal via activation of the reticular-thalamic activating system. This entrainment can also be measured within the cerebral cortex by EEG recording.

Cerebral activity as recorded by EEG is conventionally divided into four categories. The most rapid pattern is that of the beta pattern, with a frequency of 14 Hz to > 100 Hz. This is the pattern of normal waking consciousness and is associated with concentration, alertness, arousal and cognition. At higher levels, the beta pattern is associated with anxiety. The delta EEG pattern (0.1–4 Hz) is associated with dreamless sleep, the theta pattern (4–8 Hz) with random eye movement (REM) sleep, meditation and creativity and the alpha pattern (8–13 Hz) with relaxation. Therefore, through brain entrainment, a 10 Hz binaural beat would encourage the brain to

produce a 10 Hz beat corresponding to a relaxed (alpha) state of consciousness.

Our aim was to explore the potential for the use of binaural beat audio to decrease acute pre-operative anxiety. This study suggests that binaural beat audio has the potential to produce anxiolysis in many preprocedural hospital settings in which pharmacological sedation is undesirable. The decrease in acute anxiety in our Audio Group is in keeping with that reported by Wang *et al.* [9], although with some measures we were unable to reproduce evidence that audio decreases anxiety significantly compared with no intervention. This may be due to the unexpected decrease in anxiety in our control group, members of which received no intervention, which may in turn be an effect of study participation. Alternatively, it has been shown that music selected by the individual is more effective at decreasing anxiety, and our participants were denied this choice for the purposes of blinding the study. Le Scouarnec *et al.* [12] reported a decrease in acute anxiety from a mean of 41.1% to 21.2% in chronic anxiety sufferers listening to audio rich in delta-wave entrainment. Our results were consistent with the finding that acute anxiety is approximately halved using appropriate binaural beat audio.

We chose not to measure objective parameters associated with acute anxiety. Measuring physiological variables associated with stress in the immediate pre-operative period, such as pulse, blood pressure, respiratory rate, catecholamine and cortisol blood levels, and skin conductance, correlates poorly with subjective changes in acute pre-operative anxiety [9]. Reasons for this are unclear. As this was an initial investigation exploring the potential of binaural beat audio, we did not extend the study to examine the impact of anxiety levels on anaesthetic requirements or patient satisfaction, although it would be interesting to conduct such a follow-up study.

Our experimental version of binaural beat audio lasted for 30 min. The commercial version has a 60-min duration maintaining entrainment of delta brain waves for a total of 40 min, providing greater flexibility regarding the timing of application and its cessation. For example, highly anxious individuals could listen to binaural beat audio for up to 1 h until immediately before induction of anaesthesia.

This study suggests that offering binaural beat audio before day case procedures might serve to bring about anxiolysis in the majority of patients without impacting adversely on postoperative functioning.

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